

REMARKS

The Examiner's advise that the text of the Office Action from the first line of page 7 to page 11, line 3 from the bottom were inadvertently included and should be ignored is appreciated.

It has been noted that no claim 39 was previously presented. Accordingly, the claim number of each claim previously presented as claims 40-49 has been reduced by one and the dependency corrected.

A brief description of the drawings has been added to the specification. Withdrawal of the objection based on its absence is respectfully requested.

It is respectfully submitted that all rejections based on 35 U.S.C. § 112 can be withdrawn.

Claim 38 has been amended so that the reference to mole percentages tracks the disclosure on the bottom of page 5. Also, claims directed to the preference for at least one of the two compounds of formula II to have R³ and R⁴ groups which are saturated, i.e., have a value of f which is 0 (see page 5, lines 3-4), have been presented.

The R⁵ group is a connector between CH₂- and -X¹ moieties. It can be a divalent group or absent. Those skilled in the art will clearly understand that when it is absent, these two moieties are directly connected and R⁵ would designate a bond (page 4, line 6) in this instance. The specification does provide sufficient support for the language employed.

On page 4 of the Office Action, the Examiner indicated that the application enabled a method of eliciting a mucosal response in a mammal by orally administering the composition. To avoid unnecessary dispute, the language used by the Examiner has been incorporated into the claims and based on the working examples, it has been

indicated that the response is IgA. Claims specifying the mammal as human (page 9, line 2) have been added to the application.

The rejection under 35 U.S.C. § 102(b) or 103 over the applicant's PCT application is respectfully traversed.

The claims under consideration are directed to a method of eliciting an IgA response in a mammal by orally administering the particular composition specified in the claims. No such method is taught or suggested in the reference. Instead, the reference is particularly directed to certain ionic liposomes which can be administered by virtually any mode of administration to induce an IgG immune response and possibly for delivery of genes for other applications. While oral administration is, of course, mentioned in the reference, all of the examples in that reference administer the liposomes by injection. There is no teaching or suggestion that if compositions are administered orally, they would be effective to generate an IgA response. In order for an oral composition to generate an IgA response, as in the present invention, the composition must be constructed in a way that enables the composition to survive in the gut long enough to facilitate the uptake of a proportion by the Peyer's patches and M cells. There is nothing in the reference which teaches or suggests that the compositions would be adequately stable in the intestinal system to allow absorption if orally administered.

Further, there is one composition falling within the scope of the instant claims in example 7 of the reference but that composition was injected intramuscularly and is shown to be less effective than other compositions having different liposome forming components. It is respectfully submitted that that the teachings of the reference would have discouraged those skilled in the art from even trying the claimed method and even for some unknown reason, one decided to try, there is inadequate information in the reference to allow one to select a particular liposome composition to

be used orally with any expectation of successfully generating an IgA response. In any event, obvious to try is inadequate to negate patentability.

In light of all of the foregoing considerations, it is respectfully submitted that this application is in condition to be allowed and the early issuance of a Notice of Allowance is respectfully solicited.

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Respectfully submitted,

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